



IFW

DOCKET NO.: MOR-0277

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Nicholas C. Nicolaides, et al.

Application No.: 10/813,502

Filing Date: March 30, 2004

Confirmation No.: 5311

Group Art Unit: 1653

Examiner: Not Yet Assigned

For: METHOD FOR GENERATING GENETICALLY ALTERED ANTIGENS

DATE OF DEPOSIT: June 15, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Elizabeth A. McLoud

TYPED NAME: Elizabeth A. McLoud

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached; or
- ☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
- ☐ Certification in Accordance with § 1.97(e) is attached;
- or
- ☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.
- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).
- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☒ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

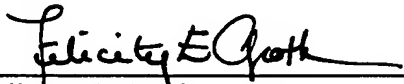
EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1-87, 89-95** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/712,691**, filed **November 14, 2000** now **U.S. Patent No. 6,737,268**.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date: June 15, 2004



Felicity E. Groth
Registration No. 47,042

WOODCOCK WASHBURN LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439



Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277	Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.	
	Filing Date March 30, 2004	Group 1653
	Confirmation No. 5311	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	1	Allen, D., et al., "MutS mediates heteroduplex loop formation by a translocation mechanism," <i>EMBO J.</i> , 1997, 16(14), 4467-4476
	2	Anders, R.F., "Part iv: Vaccines against asexual blood stages of plasmodium falciparum," <i>New Generation Vaccines</i> , 2 nd Ed., Revised and Expanded, 1997, 1035-1055
	3	Anderson Human gene therapy, 1998, 25-30
	4	Aronshtam, A., et al. "Dominant negative mutator mutations in the mutL gene of Escherichia coli", <i>Nucleic Acids Research</i> , 1996, 24(13), pp 2498-2504
	5	Ausiello, C.M., et al., "Cell-mediated immune responses in four-year-old children after primary immunization with acellular pertussis vaccines," <i>Infection and Immunity</i> , 1999, 67(8), 4064-4071
	6	Baker, S.M., et al., "Male mice defective in the DNA mismatch repair gene PMS2 exhibit abnormal chromosome synapsis in meiosis," <i>Cell</i> , 1995, 82, 309-319
	7	Bell, C.J., et al., "Assignment of 30 microsatellite loci to the linkage map of <i>arabidopsis</i> ," <i>Enomics</i> , 1994, 19, 137-144
	8	Bishop Chromosomal insertion of foreign DNA, 1996, 607-619
	9	Bjornson, K., et al., "Modulation of MutS ATP hydrolysis by DNA cofactors," <i>Biochemistry</i> , 2000, 39, 3176-3183
	10	Bork, <i>Genome Research</i> , 2000, 10, 398-400
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277		Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.		
	Filing Date March 30, 2004		Group 1653
	Confirmation No. 5311		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	11	Bork, <i>Trends in Genetics</i> , 1996, 12, 425-427	
	12	Boyce, T.G., et al., "Safety and immunogenicity of adjuvanted and unadjuvanted subunit influenza vaccines administered intranasally to healthy adults," <i>Vaccine</i> , 2001, 19, 217-226	
	13	Brenner, <i>Trends in Genetics</i> , 1999, 15, 132	
	14	Bronner C.E., et al., "Mutation in the DNA mismatch repair gene homologue hMLH1 is associated with hereditary non-polyposis colon cancer," <i>Nature</i> , 1994, 368, 258-261	
	15	Brostoff, S., "The development and use of T cell receptor peptide vaccines," <i>Immun. Of Proteins and Peptides VIII</i> , 1995, 249-254	
	16	Cascalho M, et al. "Mismatch repair co-opted by hypermutation", <i>Science</i> , 1998, 279(20), pp 1207-1210	
	17	Chakravarti, D. et al., "Relating aromatic hydrocarbon-induced DNA adducts and c-H-ras mutations in mouse skin papillomas: The role of apurinic sites", <i>Proc. Natl. Acad. Sci. USA</i> , October 1995, Vol. 92, pp. 10422-10426	
	18	Corbel, M.J., "Reasons for instability of bacterial vaccines," <i>Dev. Biol. Stand.</i> , 1996, 87, 113-124	
	19	Culligan, K.M., et al., "DNA mismatch repair in plants," <i>Plant Physiol.</i> , 1997, 15, XP-002099372, 833-839	
	20	Devos, R., et al., "Molecular cloning of human interleukin 2cDNA and its expression in <i>E. coli</i> , <i>Nucleic Acids Research</i> , 1983, 11(13), 4307-4323	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277	Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.	
	Filing Date March 30, 2004	Group 1653
	Confirmation No. 5311	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
21	de Wind, N., et al., "Inactivation of the mouse Msh2 gene results in mismatch repair deficiency, methylation tolerance, hyperrecombination, and predisposition to cancer," <i>Cell</i> , 1995 , 82, 321-330	
22	Drummond, J.T., et al., "Isolation of an hMSH2-p160 heterodimer that restores DNA mismatch repair to tumor cells," <i>Science</i> , 1995 , 268, 1909-1912	
23	Drummond, J.T., et al., "Cisplatin and adriamycin resistance are associated with mutL α and mismatch repair deficiency in an ovarian tumor cell line," <i>J. Biological Chemistry</i> , 1996 , 271(33), 19645-19648	
24	Edelmann, W., et al., "Meiotic pachytene arrest in MLH1-deficient mice," <i>Cell</i> , 1996 , 85, 1125-1134	
25	Eshleman, J.R., et al., "Mismatch repair defects in human carcinogenesis," <i>Human Molecular Genetics</i> , 1996 , 5, 1489-1494	
26	Fishel, R., et al., "the human mutator gene homolog MSH2 and its association with hereditary nonpolyposis colon cancer," <i>Cell</i> , 1993 , 7, 1027-1038	
27	Galio, L., et al., "ATP hydrolysis-dependent formation of a dynamic ternary nucleoprotein complex with MutS and MutL," <i>Nucleic Acids Research</i> , 1999 , 27(11), 2325-2331	
28	Grasso, L., "Molecular analysis of human interleukin-9 receptor transcripts in peripheral blood mononuclear cells," <i>J. Biological Chemistry</i> , 1998 , 273(37), 24016-24024	
29	Hamilton, S.R., et al., "The molecular basis of turcot's syndrome," <i>N. Eng. J. Med.</i> , 1995 , 332(13), 839-847	
30	Harfe, B.D., "DNA mismatch repair and genetic instability," <i>Annu. Rev. Genet.</i> , 2000 , 34, 359-399	
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. MOR-0277	Application No. 10/813,502
		Applicant Nicholas C. Nicolaides, et al.	
		Filing Date March 30, 2004	Group 1653
		Confirmation No. 5311	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	31	Hoang, J., et al., "BAT-26, an indicator of the replication error phenotype in colorectal cancers and cell lines," <i>Cancer Research</i> , 1997, 57, 300-303	
	32	Honma, M., et al., "Cytotoxic and mutagenic responses to X-rays and chemical mutagens in normal and p53-mutated human lymphoblastoid cells," <i>Mutation Research</i> , 1997, 374, 89-98	
	33	Jean, M., et al., "Isolation and characterization of <i>AtMLH1</i> , a <i>MutL</i> homologue from <i>Arabidopsis thaliana</i> ," <i>Mol. Gen. Genet.</i> , 1999, 262, XP-000986138, 633-642	
	34	Jiricny, J., et al., "Mismatch repair defects in cancer," <i>Curr. Opin. Genet. Dev.</i> , 2000, 10, 157-161	
	35	John, T.M., "The final stages of the global eradication of polio," <i>New England Journal of Medicine</i> , 2000, 806-807	
	36	Karran, P., et al., "Genomic instability and tolerance to alkylating agents," <i>Cancer Surveys</i> , 1996, 28, 69-71	
	37	Kim, K., et al., "Conformationally appropriate expression of the toxoplasma antigen SAG1 (p30) in CHO cells," <i>Infection and Immunity</i> , 1994, 62(1), 203-209	
	38	Kniskern, P.J., et al., "Characterization and evaluation of a recombinant hepatitis B vaccine expressed in yeast defective for N-linked hyperglycosylation," <i>Vaccine</i> , 1994, 12(11), 1021-1025	
	39	Kong, Q., "PMS2-deficiency diminishes hypermutation of a λ_1 transgene in young but not older mice," <i>Molecular Immunology</i> 36, 1999, 83-91	
	40	Leach, F.S., et al., "Mutations of a mutS homolog in hereditary nonpolyposis colorectal cancer," <i>Cell</i> , 1993, 75, 1215-1225	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277	Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.	
	Filing Date March 30, 2004	Group 1653
	Confirmation No. 5311	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	41	Lechmann, M., et al., "Vaccine development for hepatitis C," <i>Seminars in Liver Disease</i> , 2000 , 20(2), 211-226
	42	Lipkin, S.M., et al., "MLH3: a DNA mismatch repair gene associated with mammalian microsatellite instability," <i>Nature Genetics</i> , 2000 , 24, XP-002165243, 27-35
	43	Liu, T., et al., "Microsatellite instability as a predictor of a mutation in a DNA mismatch repair gene in familial colorectal cancer," <i>Genes, Chromosomes & Cancer</i> , 2000 , 27, 17-25
	44	Liu et al., "Analysis of Mismatch Repair Genes in Hereditary Non-polyposis Colorectal Cancer Patients", <i>Nature Medicine</i> , February 1996 , 2(2), 169-174
	45	Ma et al., "Dominant Negative Expression of hPMS2 Creates Isogenic Mismatch Repair Deficient Human Colon Cancer Cell Lines", <i>Proc. Am. Assoc. Cancer Res.</i> , March 1998 , 39, p. 460 (Abstract #3130)
	46	McCallum, C.M., "Targeted screening for induced mutations," <i>Nature Biotechnology</i> , 2000 , 18, 455-457
	47	McLeod, R., et al., "Immunogenetics in the analysis of resistance to intracellular pathogens," <i>Current Opinion in Immunology</i> , ISSN 0952-7915, 1995 , 7, 539-552
	48	Modrich, P., "Mismatch repair, genetic stability, and cancer," <i>Science</i> , 1994 , 266, 1959-1960
	49	Neuberger, M., et al., "Mice perform a human repertoire," <i>Nature</i> , 1997 , 386, 25-26
	50	Ngo, et al., "Computational complexity, protein structure prediction, and the levinthal paradox," 1994 , 491-495
EXAMINER		DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277		Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.		
	Filing Date March 30, 2004		Group 1653
	Confirmation No. 5311		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	51	Nicolaides, N.C., et al., "Analysis of the 5' region of <i>PMS2</i> reveals heterogeneous transcripts and a novel overlapping gene," <i>Genomics</i> , 1995 , 29, 329-334	
	52	Nicolaides, N.C., et al., "Molecular cloning of the N-Terminus of GTBP," <i>Genomics</i> , 1996 , 31, 395-397	
	53	Nicolaides, N.C., et al., "Genomic organization of the human <i>PMS2</i> gene family," <i>Genomics</i> , 1995 , 30, 195-206	
	54	Nicolaides, N.C., "A naturally occurring <i>hPMS2</i> mutation can confer a dominant negative nutator phenotype," <i>Mol. Cell. Biol.</i> , 1998 , 18(3), 1635-1641	
	55	Nicolaides, N.C., et al., "The jun family members, c-jun and junD, transactivate the human <i>c-myb</i> , promotor via an Ap1-like element," <i>J. Biological Chemistry</i> , 1992 , 267(27), 19655-19672	
	56	Nicolaides, N.C., et al., "Positive autoregulation of <i>c-myb</i> , expression via Myb binding sites in the 5' flanking region of the human <i>c-myb</i> gene," <i>Molecular and Cellular Biology</i> , 1991 , 11(12), 6166-6176	
	57	Nicolaides, N.C., et al., "Mutations of two PMS homologues in hereditary nonpolyposis colon cancer," <i>Nature</i> , 1994 , 371, 75-80	
	58	Nicolaides, N.C., et al., "Interleukin 9: A candidate gene for asthma," <i>Proc. Nat. Acad. Sci. USA</i> , 1997 , 94, 13175-13180	
	59	Orenstein, W.A., et al., "Measles eradication: Is it in our future," <i>Am. J. Public Health</i> , 2000 , 90(10), 1521-1524	
	60	Palombo, F., et al., "Mismatch repair and cancer," <i>Nature</i> , 1994 , 367, 417	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. MOR-0277		Application No. 10/813,502
	Applicant Nicholas C. Nicolaides, et al.		
	Filing Date March 30, 2004		Group 1653
	Confirmation No. 5311		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	61	Papadopoulos, N., et al., "Mutation of a <i>mutL</i> homolog in hereditary colon cancer," <i>Science</i> , 1994 , 263, 1625-1629	
	62	Papadopoulos, N., et al., "Mutations of <i>GTBP</i> in genetically unstable cells," <i>Science</i> , 1995 , 268, 1915-1917	
	63	Parsons, R., et al., "hypermutability and mismatch repair deficiency in RER+ tumor cells," <i>Cell</i> , 1993 , 75, 1227-1236	
	64	Parsons, R., et al., "Mismatch repair deficiency in phenotypically normal human cells," <i>Science</i> , 1995 , 268, 738-740	
	65	Peinado, M.A., et al., "Isolation and characterization of allelic losses and gains in colorectal tumors by arbitrarily primed polymerase chain reaction," <i>Proc. Natl. Acad. Sci. USA</i> , 1992 , 89, 10065-10069	
	66	Perucho, M., et al., "Cancer of the microsatellite mutator phenotype," <i>Biol. Chem.</i> , 1996 , 377, 675-684	
	67	Polaczek, P., et al., "Functional genetic tests of DNA mismatch repair protein activity in <i>saccharomyces cerevisiae</i> ," <i>Gene</i> , 1998 , 213(1-2), 159-167	
	68	Polejaeva, et al., "New advances in somatic cell nuclear transfer application in transgenesis," 2000 , 117-126	
	69	Prolla, T.A., et al., "MLH1, PMS1, and MSH2 interactions during the initiation of DNA mismatch repair in yeast," <i>Science</i> , 1994 , 265, 1091-1093	
	70	Quian, Y. et al., "Molecular events after antisense inhibition of hMSH2 in a HeLa cell line", <i>Mutation Research</i> , October 12, 1998 , Vol. 418, pp. 61-71	
EXAMINER			DATE CONSIDERED

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office		Docket No. MOR-0277	Application No. 10/813,502
		Applicant Nicholas C. Nicolaides, et al.	
		Filing Date March 30, 2004	Group 1653
		Confirmation No. 5311	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	71	Rulicke, et al., "Special review series-gene manipulation and integrative physiology," 1996 , 589-600	
	72	Russell, et al., "Structural features can be unconserved in proteins with similar folds," 1994 , 332-350	
	73	Schrader, C.E., et al., "Reduced isotype switching in splenic B cells from mice deficient in mismatch repair enzymes," <i>J. Exp. Med.</i> , 1999 , 323-330	
	74	Sela, M., "Structural components responsible for peptide antigenicity," <i>Applied Biochemistry and Biotechnology</i> , 2000 , 83, Catalytic and Superantibodies, 63-70	
	75	Spampinato, C., et al., "The MutL ATPase is required for mismatch repair," <i>J. Biological Chemistry</i> , 2000 , 275(13), 9863-9869	
	76	Strand, M., et al., "Destabilization of tracts of simple repetitive DNA in yeast by mutations affecting DNA mismatch repair," <i>Nature</i> , 1993 , 365, 274-276	
	77	Su, S., et al., "Dispair specificity of methyl-directed DNA mismatch correction In Vitro," <i>J. Biological Chemistry</i> , 1988 , 263(14), 6829-6835	
	78	Verma, et al., "Gene therapy promises, problems and prospects," 1997 , 389, 239-242	
	79	Vora, K.A., et al., "Severe attenuation of the B cell immune response in Msh2-deficient mice," <i>J. Exp. Med.</i> , 1999 , 189(3), 471-481	
	80	Wheeler, J.M.D., et al., "The role of hypermethylation of the <i>hMLH1</i> promoter region in HNPCC versus MSI+sporadic colorectal cancers," <i>J. Med. Genet.</i> , 2000 , 588-592	
	81	Winter, D.B., et al., "Altered spectra of hypermutation in antibodies from mice deficient for the DNA mismatch repair protein PMS2," <i>Proc. Natl. Acad. Sci. USA</i> , 1998 , 95, 6953-6958	
	82	Yu, Y. et al., "Adriamycin induces large deletions as a major type of mutation in CHO cells", <i>Mutation Research</i> , November 1994 , Vol. 325, pp. 91-98	
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office				Docket No. MOR-0277		Application No. 10/813,502	
				Applicant Nicholas C. Nicolaides, et al.			
				Filing Date March 30, 2004		Group 1653	
				Confirmation No. 5311			
U. S. PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Name	Class	Subclass	
	83	5,885,827	03/23/99	Wabl, et al.	435	320.1	
	84	5,907,079	05/25/99	Mak et al.	800	2	
	85	6,146,894	11/14/00	Nicolaides, et al.	435	440	
	86	6,191,268 B1	02/20/01	Liskay et al.	536	23.5	
	87	6,287,862 B1	09/11/91	delCardayre, et al.	435	440	
	88	6,737,268	05/18/04	Nicolaides, et al.	435	325	
	89	2002/0055106	05/2002	Nicolaides, et al.	435	6	
	90	2002/0068284	06/2002	Nicolaides, et al.	435	6	
	91	2002/0128460	09/2002	Nicolaides, et al.	536	23	
FOREIGN PATENT DOCUMENTS							
Examiner Initial		Document No.	Date	Country	Translation		
					YES	NO	
	92	WO 97/05268	02/13/97	PCT			
	93	WO 97/08312	03/06/97	PCT			
	94	WO 99/19492	04/22/99	PCT			
	95	2 240 609	10/14/99	Canada			
EXAMINER				DATE CONSIDERED			